

AB providing a sleeve formed from an expandable material and having opposed open ends, the sleeve being dimensioned for constricting the body tissue to suppress leakage of at least one of body fluid and air, and including an X-ray opaque material visible under X-ray fluoroscopy;

drawing the body tissue into the sleeve to contain, confine and constrict the body tissue within the sleeve; and

confirming the continued constriction of the body tissue by fluoroscopically visualizing the X-ray opaque material.

IN THE DRAWINGS

Please consider the following proposed corrected drawing attached to this Amendment and Response: Figure 4.

REMARKS

As filed, the Application included claims 1-14. Claim 14 has been amended by this paper, no claims were added by preliminary amendment, and no claims stand withdrawn from consideration. New claims 15 and 16 have been added by this paper. Hence, the Application now includes claims 1-16 for examination. In view of the following arguments and citations, allowance of all claims is respectfully requested.

Drawings

The Examiner objected to the drawings in paragraph 1 of the Office Action because Figure 4 does not label the line 5-5. A proposed drawing correction has been furnished with this paper labeling the line 5-5, and a letter to the draftsman is further enclosed.


Claim Rejection - 35 USC § 112

Claim 14 stands rejected in paragraphs 2 and 3 of the Office Action under 35 USC § 112, second paragraph, as failing to specify a function of the means claim.

Claim 14 is amended to specify a function of the means claim, and favorable reconsideration is respectfully requested.

Claim Rejection - 35 USC § 102(e)

Claims 1-9, 11, 13, and 14 stand rejected in paragraphs 4 and 5 under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,126,590 to Alferness (hereinafter Alferness). (Mr. Alferness is a co-inventor on the instant application, and will not be referred to individually in conjunction with the instant invention.)

Alferness is directed to a cardiac reinforcement or support jacket. The Alferness jacket is applied over a heart to confine and preclude expansion of the heart as a therapy for ventricular dilation. While Alferness' support jacket can be made from inflexible material, it is preferably sufficiently flexible to move with the expansion and contraction of the heart without impairing cardiac function. Col. 3, lines 16-19. 

Alferness describes his device as a cardiac reinforcement device or jacket (CRD) that limits the outward expansion of the heart wall during diastolic chamber filling beyond a predetermined size. Col. 3, lines 1-3. Alferness' jacket is opened for application to the heart and closed for wearing. Alferness' device might be compared to a cardigan jacket that is opened at the chest to put on over a person's head and shoulders, and the opening at the chest closed with drawstrings or fasteners for wearing. See Alferness at Figure 3 showing string fasteners numbers 22 and 23 for adjusting the volume of and closing the jacket; and at Figure 8 showing a lateral attachment cord 80 that is pulled to reduce the size of, and to secure, the jacket. Further, Figure 3 shows that the structure of Alferness requires a "circumferential attachment device 17" at the base of the jacket to keep it on the heart.

The express purpose of the Alferness device is to improve the function of the heart in those areas of the heart where the jacket is applied. While the Alferness jacket does confine the heart to reinforce or support the heart, it neither collapses nor constricts the heart. To do so would obviously render the heart nonfunctional and kill the patient. Alferness includes making certain jacket material radio opaque "by inclusion of markers for identification or visualization of the outside surface of the heart,

th expansion sl t, or inflation port." Col. 5, lines 25-27. Th visualization of the h art surface and portions of the jacket are requir d to monitor th amount of heart constraint r dilation accomplished over time. Col. 7, lines 15-19.

The present application is an improvement to the invention that is the subject matter of Serial Number 09/534,244, which is identified in the instant application, and which matured into issued United States Patent No. 6,328,689 B1. Two other co-p nding applications are also an improvement to the same invention: CONstriction DEVICE INCLUDING FIXATION STRUCTURES, Serial Number 09/902,821; and TISSUE RESECTION DEVICE, SYSTEM AND METHOD, Serial Number 09/780,232. In contrast with Alferness, one aspect of the present invention as defined in independent claims 1, 14, 15 and 16, and as is consistent with the above patent and copending applications, is the constriction of a body tissue for treatment of leakage, such as air, using an elongated sleeve.

A device according to the present invention contains, confines, and importantly constricts the selected body tissue to prevent leaks. The body tissue is drawn into an elongated sleeve whose inside diameter has been elastically expanded. The sleeve is released from its expanded condition and the elasticity of the sleeve returns the inside diameter of the sleeve towards its native diameter, constricting the body tissue therein in the process. The constriction forms and maintains a seal without otherwise requiring traditional methods of suturing, gluing, or other closure methods that can often be fraught with complications. Such potential complications include creating additional leaks of air, body fluid such as blood, contaminates, or other adverse results. The constricted tissue obviously will become ischemic and necrotic.

The common definition of the words "constrict" and its derivative "constriction" is used on the specifications. A common meaning of "constrict" as defined in *The New Oxford American Dictionary* 368 (2001) is to "make narrower, esp. by encircling pressure." "Sleeve" as used in the application denotes a structure that wholly or partially covers the body tissue for constriction. The sleeve structure is further defined as being "elongated," which has its common meaning of having an axial length that is long in relation to its diameter. The "elongated sleeve" limitation of the independent

claims is illustrated in Figures 3, 4, 6-9, and 12-14, and particularly with reference to reference numbers 72 and 74 of Figure 3. The elongated sleeve structure of the instant invention is particularly useful for constricting lung tissue and other body organs having more than a single vessel such as a blood vessel or air passageway. For example, lung tissue has many small blood vessels and air passageways that are difficult to seal against leakage. The elongated sleeve structure provides constriction and support over a length of the body tissue. The sleeve structure also will inherently limit any tendency to roll off the body tissue.

The independent and dependent claims additionally define important aspects of visualization of the constriction device with radio opaque materials. The ability to fluoroscopically view the constriction device provides an improvement and several advantages over the invention of issued United States Patent No. 6,328,689 B1. For example, a physician can visually confirm that the constriction device is properly positioned to constrict the body tissue, and conclude the procedure with a measure of confidence that the sleeve will remain on the body tissue and provide constriction to suppress leakage. By way of a further example of advantages, the fluoroscopically viewable elements enable a physician to confirm continued post-operative placement of a sleeve.

Applicants submit that the claims of the present invention are not anticipated by Alferness. Alferness fails to teach all the structural limitations of the present claims. MPEP § 2114. To anticipate, Alferness must be an identical invention in every detail. MPEP § 2131. "To anticipate under section 102, a prior art reference must disclose all the elements of the claimed invention or their equivalents functioning in essentially the same way." *Shanklin Corp. v. Springfield Photo Mount Co.*, 521 F.2d 609, 187 U.S.P.Q. 129 (1st Cir. 1975). "Not only must all the claimed elements be present in the prior device, but the elements must be found in substantially the same situation where they do substantially the same work." *Gillette v. Warner-Lambert Co.*, 690 F. Supp. 115, 117, 8 U.S.P.Q. 1082, 1084 (D. Mass 1988). "Thus, any degree of physical difference between the patented product and the prior art, *no matter how slight*, defeats the claim of anticipation. *American Permahedge, Inc. v. Barcana, Inc.*, 857 F. Supp. 308, 32

U.S.P.Q. 1801, 1807-08 (S.D.N.Y. 1994). A basis for non-anticipation by the instant claims over Alferness is that the constriction provided by the sleeve structure of the instant claims enables suppression of leaks. The independent claims of the instant application claim a body tissue constriction method and device that is configured to contain and constrict a body tissue, the body tissue typically being part of an organ. The constriction suppresses leaks, internal bleeding and escape of body fluids. The Alferness device is neither suited nor described as being potentially suited for this purpose. Such constriction with the Alferness device would render the heart non-functional. Clearly not an intended result in Alferness.

From the above, it is respectfully submitted that the Alferness jacket is completely different in structure and function from the body tissue constriction device defined in original claims 1 and 14. The elements of the instant invention are not functioning in essentially the same way as Alferness. Furthermore, the elements are not found in substantially the same situation where they do substantially the same work. New device claim 15 and new method claim 16 were added to even more clearly distinguish the claims over the prior art by claiming that the sleeve suppresses leakage of at least one of body fluid and air. The preambles of independent claims clearly express that the expandable property of the device performs an entirely different purpose, i.e., constriction of the body tissue. This is not described in Alferness, and would be directly contrary to the expressed purpose and function of the Alferness device.

Another basis for non-anticipation by the instant claims over Alferness is that Alferness does not provide a constricting sleeve structure that is expandable. The Office Action alleges at paragraph 5 that Alferness describes the heart reinforcement jacket as being formed from expandable material. However, that is not what Alferness describes. Alferness merely describes his jacket as being size adjustable. Alferness only provides a size adjustable, cardiac reinforcement material dimensioned so that it can be expanded to jacket (and support and reinforce) the epicardial surface of the heart, and prevent expansion of the heart beyond a limit established by the configuration of the jacket. Col. 1, lines 60-62; and col. 4, lines 12-22. Alferness

describes his device as being expandable to a predetermined size to constrain cardiac expansion (column 1, lines 55-59) and to move with the expansion and contraction of the heart to avoid impairing systolic function (column 3, lines 12-13). Nowhere does Alferness show, describe, or even suggest constricting the heart with his device for sealing a leak. Drawing further on the analogy of a cardigan jacket, it would be a misuse of words to characterize the jacket, open in preparation for putting on, as being in an "expanded condition," and a further misuse of words to characterize fastening or drawing the opening portion of the jacket closed as "released from the expanded condition."

A further basis for non-anticipation by the instant claims over Alferness is that Alferness fails to show, describe, or even suggest the "elongated sleeve" as defined in the claims. The "elongated sleeve" is structurally suited for constricting and supporting body tissue to prevent leakage of air and blood. The "elongated sleeve" of the instant invention is structurally resistant to rolling off the body tissue because of its elongated configuration, and eliminates the "circumferential attachment device 17" structure shown in Figure 3 of Alferness required to keep the jacket on the heart.

From the above, it is respectfully submitted that all claims to the device and method defined in independent claims 1, 14, 15 and 16 are clearly allowable over Alferness. Alferness fails to describe, show, or suggest the invention defined in these claims. New claims 15 and 16 were added to even more clearly distinguish the claims over the prior art. Claim 15 includes a limitation that the constriction is against leakage. Claim 16 defines a method for suppressing leakage as described in the Application. Favorable consideration is respectfully requested.

Claim Rejection - 35 USC § 103

Dependent claims 10 and 12 stand rejected in paragraphs 6 and 7 under 35 USC § 103(a) as being obvious and unpatentable over U.S. Patent No. 6,126,590 to Alferness.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the

art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP 2142.

Not a requirement

Claims 10 and 12 depend from claim 1 by way of claim 8. Previous portions of this paper have responded showing the differences in structure and function between the invention as defined in independent claim 1 over Alferness. Alferness does not meet the three basic criteria. Alferness does not show, teach, or suggest adding a visualization element to a constricting device for pre- or post-surgical visual confirmation that the constriction device is properly positioned to constrict the body tissue to suppress leakage.

In view of the foregoing, it is respectfully submitted that dependent claims 10 and 12 are allowable over Alferness. Favorable reconsideration is respectfully requested.

CONCLUSION

Original claims 1-14 remain in the application, and new claims 15 and 16 have been presented here for examination. For the foregoing reasons, it is respectfully submitted that existing claims 1 and 14, and new claims 15 and 16 are in condition for allowance. Since the remaining claims are dependent from these claims, these claims are likewise considered to be in condition for allowance.

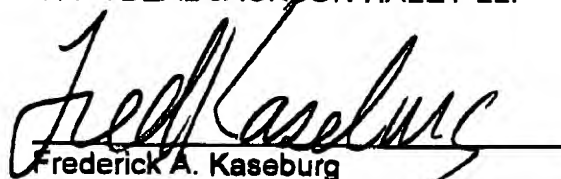
By the foregoing, this paper responds fully to all of the concerns expressed in the Office Action, and has demonstrated that each of the pending claims is in condition for immediate allowance. Favorable reconsideration and allowance of the pending claims are therefore respectfully requested.

You are hereby authorized to charge the fee of \$42 for one of the two additional new independent claims (one independent claim over three), and to charge any additional fees that may be due, to Deposit Account No. 07-1897.

If the Examiner believes that a phone interview would be helpful, a phone call to the undersigned at (425) 455-5575 is respectfully encouraged.

Respectfully submitted,

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Attachments: Redline marked version of amended claim 14.
Marked Figure 4
Letter to Draftsperson

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Marked-up version of amended claim

14. A constriction device that constricts body tissue, the device comprising:
sleeve sleeve means for receiving therein a body tissue to be constricted when in
an expanded condition, and for constricting the body tissue therein when released from
the expanded condition; and

means for ~~including opposed opened ends and formed from expandable material to~~
~~receive therein, when in an expanded condition, body tissue to be constricted and to~~
~~constrict the body tissue therein when released from the expanded condition, and X ray~~
~~opaque means for rendering the device visible under X ray fluoroscopy.~~